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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,836	03/16/2001	Pierre Broun	MBI-0032	7074
20872	7590	12/03/2003	EXAMINER	
MORRISON & FOERSTER LLP			LAMBERTSON, DAVID A	
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1636

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/810,836	Applicant(s) BROUN, PIERRE	
	Examiner David A. Lambertson	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,13-33 and 35-50 is/are pending in the application.
- 4a) Of the above claim(s) 19-25 and 27-32 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 3-11,13-15,18,26,33 and 35-50 is/are rejected.
- 7) ☒ Claim(s) 16 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed September 9, 2003. Amendments were made to the claims. Specifically, claims 2 and 34 were cancelled.

Claims 1, 3-11, 13-33 and 35-50 are pending in the instant application. Claims 2, 12 and 34 have been cancelled. Claims 19-25 and 27-32 are withdrawn from further consideration. Claims 1, 3-11, 13-18, 26, 33 and 35-50 are ready for examination in the instant application. Any rejection of record in the previous Office Action, mailed May 23, 2003, that is not addressed in this action has been withdrawn.

Applicant contends that the previous amendment, filed June 16, 2003, was in full compliance with the amendment practice at the time, and that the Examiner erred in mailing an Notice of Non-Responsiveness. Applicant's argument is based solely on the fact that they had until July 30, 2003 to submit amendments compliant with the previous version of amendment practice under 37 CFR 1.121. Applicant further states that they reserve the right to request a patent term extension for the delay brought about by the Notice of Non-responsiveness. In response, the examiner wishes to acknowledge that, although Applicant did have until July 30, 2003 to submit amendments compliant with the previous version of amendment practice under 37 CFR 1.121, the response filed June 16, 2003 *was not in compliance with either the previous version of amendment practice or the interim revised amendment practice*. This is because the previous amendment did not contain an *unmarked clean copy* of the amended claims (thus not complying with the previous amendment practice), nor did the amendment properly indicate the status of all claims that were pending in the application at any time during practice (thus not

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complying with the interim amendment practice). This was clearly set forth in the Notice of Non-Responsiveness mailed August 11, 2003.

Specification

The disclosure is objected to because of the following informalities: several pages within the specification contain application numbers, but do not indicate the status of the application as either abandoned or patented (by indication of Patent No.). These pages are 8, 9, 11 and 17.

Appropriate correction is required.

Claim Objections

Claim 45 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, claim 45 is the same scope as claim 33 because the limitation "wherein said cell is from a plant" is already set forth in the body of claim 33 (see line 4).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 33 and 34-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 lacks a positive process step recapitulating the preamble of the claim. In the absence of such a step, it is unclear what the final step of the method is, thus the claim is indefinite as being open-ended. **This is a new rejection not necessitated by amendment.**

Claims 33, 38, 46 and 48 recite the limitation "said pathway gene promoter" in the claim (i.e., the eighth line of claim 33; note that claims 46 and 48 only recite "said promoter"). There is insufficient antecedent basis for this limitation in the claim because it is unclear if said pathway gene promoter is referring to the biosynthetic pathway gene promoter that is operably linked to a reporter gene (see lines 4-5 of the claim), or some other pathway gene promoter. It would be remedial to indicate that these promoters are the same by indicating "said biosynthetic pathway gene promoter" in the claim where "said pathway gene promoter" is recited. Please note that this amendment may raise issues of antecedent basis in dependent claims that also recite the term "said pathway gene promoter." **This is a new rejection that is necessitated by amendment.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3, 10, 11, 13 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Cen *et al.* (US 2003/0170656 A1; see entire document; henceforth Cen). It is noted that this document was not available at the time of the previous rejection, but the reference has an effective filing date prior to the effective filing date of the instant application, thereby necessitating the rejection. **This rejection is a new rejection not necessitated by amendment.**

Cen teaches an *in vivo* high throughput screening method to identify factors that modulate gene expression comprising contacting candidate factors with host cells that respond to such factors by exhibiting an intracellular event (see for example paragraphs [0004] and [0011]). Exemplary candidate factors include transcription factors (see for example paragraphs [0005] and [0012]). The cells responding to the candidate factors include plant cells, which are selected on the basis of the factors being screened (i.e., plant cells are selected when plant candidate factors are being screened) (see for example paragraph [0053]). When transcription factors are being sought, a regulatory sequence for a gene of interest (i.e., a promoter) can be operably linked to any reporter gene, such as luciferase or GFP; the presence of this reporter is then measured, thereby detecting the presence of a transcription factor in the sample being tested (see for example paragraph [0061]). In additional scenarios, the transcription levels of the gene of interest (i.e., the RNA levels of the gene) can be detected for the purpose of identifying a transcription factor in the sample (see for example paragraph [0075]). The gene of interest can be derived from any organism, including plants (see for example paragraph [0052]). The samples being tested (i.e., the source of the candidate factors) are pools of factors containing from 100-1000 factors in the form of polynucleotides, expression libraries, etc. (see for example

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paragraph [0067]) which can be transiently expressed in the host cells. Once a pool is identified to contain a transcription factor, the pool is subdivided (i.e., a deconvolution step is performed) into a smaller sub-pool of factors, and re-screened for the ability to induce expression of the gene of interest/reporter gene (see for example paragraph [0076]). Thus, Cen teaches each and every element of the claims set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cen as applied above under 35 USC § 102(e) to claim 3 (as well as claims 10, 11, 13 and 18), in view of Liu *et al.* (as recited in the previous Office Action; see entire document, henceforth Liu). **This rejection is a new rejection not necessitated by amendment.**

Cen teaches all of the elements set forth above in the rejection of claim 3 under 35 USC § 102(e). However, Cen neither teaches further detecting the expression of at least one other pathway gene in a cell (claim 4) nor the use of GUS specifically as a reporter gene (claim 14).

Liu teaches the identification of plant transcription factors, where the transcription factors are transformed into plant cells, and the expression of both the GUS gene and a second gene are detected to indicate the presence of the transcription factor (see for example the Abstract, page 1396-1397 and Figures 9 and 11).

It would have been obvious to combine the measurement of GUS and/or a second pathway gene as a reporter of transcriptional activity as taught by Liu with the assay to identify plant transcription factors taught by Cen because both assays involve the ability to measure the transcriptional activity of a candidate factor. Furthermore, Cen teaches that other reporters and genes of interest can be used to detect transcription activity in their assay, therefore the ordinary skilled artisan would have been motivated to combine the teachings because Cen suggests doing so. Absent evidence to the contrary, the ordinary skilled artisan would have had a reasonable expectation of success when measuring the expression of either GUS or a second pathway gene as a reporter for transcriptional activity.

Claims 5-9, 15, 26, 33, 36, 38-46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cen as applied above under 35 USC § 102(e) to claim 3 (as well as claims 10, 11, 13 and 18), in view of Memelink *et al.* (as cited in a previous Office Action; see entire document; henceforth Memelink). It is noted that a number of the claims set forth above do not depend from claim 3, although a number of claims do. As it regards the claims that are not dependent on claim 3, the teachings of Cen are essentially the same as those set forth in the rejection of claim 3, and are applied as such herein. **This rejection is a new rejection not necessitated by amendment.**

Cen teaches all of the elements set forth above in the rejection of claim 3 under 35 USC § 102(e). Although Cen generally teaches that their assay can be used for the identification of transcription factors that affect any gene, Cen does not specifically teach the use of a “biosynthetic pathway gene” as being the plant promoter pathway gene. This includes situations

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wherein the “biosynthetic pathway gene” is a primary or secondary pathway gene, more specifically a terpenoid or alkaloid pathway gene.

Memelink teaches the desirability of providing transcription factors to cells to increase the production of primary and secondary metabolites (see for example page 10, lines 11-19 and page 48, lines 8-22), including alkaloid and terpenoid metabolites (see for example the Abstract and page 28, line 26 to page 29, line 3). It is taught that plant primary and secondary metabolites are desirable because they are often used as pharmaceuticals, food colors, medicines, etc. (page 2, lines 18-30). However, there is a major impediment to acquiring these metabolites in that they are produced only in small amounts, therefore obtaining them is difficult, wasteful and time consuming (see for example page 3, lines 4-13). Thus, Memelink seeks to overcome this problem by supplying plant cells with transcription factors that increase the production of primary and secondary metabolites (see for example page 6, line 31 to page 7, line 10). Thus, Memelink provides the general teaching that it is desirable to have transcription factors that can increase the production of primary and secondary metabolites in cells.

It would have been obvious to use the assay for identifying transcription factors in plant cells, taught by Cen, to specifically identify transcription factors involved in biosynthetic pathways because Cen teaches that their assay can be used to identify transcription factors to regulate the expression of any gene, and Memelink teaches that there is a need for transcription factors that regulate the expression of genes involved in primary and secondary metabolite biosynthesis. The ordinary skilled artisan would have been motivated to specifically look for transcription factors that regulate biosynthetic pathways by using the assay taught by Cen because Memelink teaches that the ability to isolate primary and secondary metabolites is a great

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difficulty that can be overcome by contacting plant cells with transcription factors to increase the expression of genes involved in their synthesis, thus it would be useful to identify the transcription factors that can be used for this purpose, thus solving a long-standing problem in the field. Absent evidence to the contrary, the ordinary skilled artisan would have had a reasonable expectation of success when testing biosynthetic pathway gene promoters operably linked to a reporter to test for transcriptional activity within pools of transcription factors.

Claims 37 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cen in view of Memelink as applied above under 35 USC § 103(a) to claim 33 (and claims 5-9, 15, 26, 33, 36, 38-46 and 48), in further view of Liu. **This rejection is a new rejection not necessitated by amendment.**

Cen in view of Memelink teaches all of the elements set forth above in the rejection of claim 33 under 35 USC § 103(a). However, Cen in view of Memelink does not teach detecting the expression of at least one other pathway gene in a cell (claim 37) or the use of GUS specifically as a reporter gene (claim 47).

Liu teaches the identification of plant transcription factors, where the transcription factors are transformed into plant cells, and the expression of both the GUS gene and a second gene are detected to indicate the presence of the transcription factor (see for example the Abstract, page 1396-1397 and Figures 9 and 11).

It would have been obvious to combine the measurement of GUS and/or a second pathway gene as a reporter of transcriptional activity as taught by Liu with the assay to identify biosynthetic plant pathway transcription factors taught by Cen in view of Memelink because

both assays involve the ability to measure the transcriptional activity of a candidate factor. Furthermore, Cen in view of Memelink teaches that other reporters and genes of interest can be used to detect transcription activity in their assay, therefore the ordinary skilled artisan would have been motivated to combine the teachings because Cen in view of Memelink suggests doing so. Absent evidence to the contrary, the ordinary skilled artisan would have had a reasonable expectation of success when measuring the expression of either GUS or a second pathway gene as a reporter for transcriptional activity.

Allowable Subject Matter


Claim 1 is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson, Ph.D.
AU 1636


JAMES KETTER
PRIMARY EXAMINER